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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,905	01/29/2004	Norie Arai	ARAI=3A	2612
1444	7590	06/19/2006	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			MCINTOSH III, TRAVISS C	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 06/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/765,905

Applicant(s)

ARAI ET AL.

Examiner

Traviss C. McIntosh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 10/169,670.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite wherein the claim is drawn to “a method of regulating the mucosal immune function in humans or animals in the treatment, prevention, and alleviation of a disease”. It is unclear if applicants intended the claims to be methods of treatment, prevention, and alleviation of disease claims. It is noted that since the preamble states that the claim is drawn to a “method of regulating the mucosal immune function”, the examiner has not placed extreme weight on the limitations of “in the treatment, prevention, and alleviation of a disease”. If applicants are intending methods of treating, preventing, or alleviating a disease, it is noted that the examiner may then impose a 112 1<sup>st</sup> paragraph rejection on applicants, as it is not believed that any disease has been prevented, and alleviation reads on curing, and applicants have also not been seen to cure anything.

Claim 1 is indefinite wherein the claim is drawn to “a method of regulating the mucosal immune function in humans or animals in the treatment, prevention, and alleviation of a disease”. It is unclear as to exactly what applicants are intending with this phrase. It is unclear

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how one can treat, prevent, and alleviate a disease. If preventative therapy were used, then treatment and alleviation cannot occur, as the patient would not have contracted the disease. It is unclear how one can treat, prevent, **and** alleviate a disease. Changing the “and” to an “or” would be seen to obviate the instant rejection.

Claims 1-3 are indefinite wherein the claims are drawn to methods of regulating biological functions by administering trehalose, but the claims fail to state to whom the trehalose is to be administered. Indicating the administration is “to a patient in need thereof”, for example, would be seen to obviate the instant rejection.

Claim 5 recites the limitation “or other animal” in the 2<sup>nd</sup> line. There is insufficient antecedent basis for this limitation in the claim. Changing the phrase to read “or animal” would obviate the instant rejection.

Claim 5 is indefinite wherein the claim states that the method of claim 1 is for “the treatment of a disease, wherein said human or other animal is suffering from hepatitis A virus...”. As set forth supra, it is unclear if applicants are claiming methods of treating these diseases, or if applicants are claiming methods of treating any diseases, based on the current claim language used. It is noted that the examiner is not interpreting these claims as methods of treating these diseases, as independent claim 1 states in the preamble that the methods are for “regulating the mucosal immune function”.

Claims 4 and 5 further limit the disease of claim 1, however, as set forth supra, since these claims are not interpreted as methods of treatment claims, it is unclear how these claims are intended to limit the parent claim. That is, it is unclear how one having a disease which is an oral infectious disease, for example, will effect the methods of regulating mucosal immune function

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as claimed, as the only step required is administering trehalose to regulate immune function.

Whether the patient is suffering from rotavirus, cholera, or dysentery, for example, is not seen to affect the methods of regulating the mucosal immune function as claimed.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Nishizaki et al. ("Disaccharide trehalose inhibits bone resorption in ovariectomized mice", Nutrition Research vol. 20, no. 5, pp. 653-664, May 2000).

As set forth supra, claim 1 is being interpreted as a method of regulating the mucosal immune function in humans or animals comprising administering an effective amount of trehalose to the oral pathway. Claim 2 is drawn to a method of regulating the production of IFN- $\gamma$  in humans or animals by administering trehalose to the oral pathway. Claim 3 is drawn to a method of regulating the production of IgA in humans or animals by administering trehalose to the oral pathway. Claim 7 provides that administering is in the form of animal feed or pet food to a non-human animal.

Nishizaki et al. disclose methods wherein they administer trehalose to mice orally. It is noted that the claims only require oral administration of trehalose, the methods of regulating

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immune function would inherently occur in the mice of Nishizaki et al., as the same step was taken in each situation, oral administration of trehalose, and therefor, the same results would be expected to occur. It is noted that the amount administered in Nishizaki et al. is between 10 mg/kg and 100 mg/kg, and absent evidence to the contrary, the examiner is interpreting this as an effective amount. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). Moreover, if applicants were intended these claims as methods of treating, preventing, or alleviating a disease, this reference would still anticipate the claims, as the art could be seen as administering the compounds to prevent a disease, even if the art failed to teach the same, due to the breadth of encompassing any disease, it would be seen to inherently occur.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshizane et al. (EP 0 955 050).

The claims are drawn to methods of regulating immune function, as set forth supra.

Yoshizane et al. disclose methods of orally administering trehalose to humans and mice (see abstract, experiment 1 and experiment 2). It is noted that the administration of the same substance (trehalose) to the same population (humans) would be seen to produce the same result, as such, Yoshizane et al. is seen to inherently disclose the methods of the instant invention. It is noted that if Yoshizane et al., having taken the manipulative steps described herein, had

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attempted to measure for the results as described in the instant application, Yoshizane would have uncovered those results, as they are directly correlative to the method as practiced by Yoshizane. Applicant's discovery of differing effects of a prior art method does not give the discoverer a right to exclude others from practicing the prior arts method of orally administering trehalose, as the prior arts method would have inherently performed the method as instantly claimed. See *Ex Parte Novitski*, 26 USPQ 2d (BNA) 1389. A hypothetical example clarifies this principle. Humans lit fires for thousands of years before realizing that oxygen is necessary to create and maintain a flame. The first person to discover the necessity of oxygen certainly could not have obtained a valid patent claim for "a method of making a fire by lighting a flame in the presence of oxygen." Even if prior art on lighting fires did not disclose the importance of oxygen and one of ordinary skill in the art did not know about the importance of oxygen, understanding this law of nature would not give the discoverer a right to exclude others from practicing the prior art of making fires. *EMI v. Cypress Semiconductor*, 2001 US Fed. Cir. Ct. of App.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss C. McIntosh III  
Art Unit 1623  
June 10, 2006

A handwritten signature in black ink, appearing to read 'Traviss C. McIntosh III', with a stylized flourish at the end.